VIA EMAIL

June 9, 2020

Patricia Biggio
Office of Pesticide Programs
Pesticide Reevaluation Division (7508P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: The Hartz Mountain Corporation; Tetrachlorvinphos Mitigation –
EPA Registration Nos. 2596-49, -50, -62, -63, -78, -79, -83, -84, and -139

Dear Ms. Biggio:

On behalf of The Hartz Mountain Corporation (Hartz), I write to confirm the substance of Hartz's discussions with the Agency, especially the teleconference of June 4, 2020, concerning the above-referenced registrations of Hartz pesticide products that contain the active ingredient tetrachlorvinphos (TCVP).[1] This letter revises and updates Hartz's May 27, 2020 letter to EPA regarding the same pesticide product registrations.

Hartz has submitted and EPA has reviewed new information intended to support the continued registration of Hartz's TCVP products. In addition, EPA and Hartz have discussed how to address the Agency's concerns about the existing registrations of Hartz's TCVP products. In light of these discussions, Hartz proposes to voluntarily cancel three (3) registrations and to keep the remaining registrations in effect by implementing specific risk mitigation measures, as follows:

- **Registration No. 2596-78.** Hartz will agree to voluntarily cancel this registration according to the following schedule: Hartz will cease all production by July 31, 2020 and will continue to sell and distribute existing stocks through July 31, 2021. Hartz agrees to provide production data for the years 2018, 2019, and 2020 to EPA by September 1, 2020.

- **Registration No. 2596-79.** Hartz will agree to voluntarily cancel this registration according to the following schedule: Hartz will cease all production by July 31, 2020 and will continue to sell and distribute existing stocks through July 31, 2021. Hartz agrees to provide production data for the years 2018, 2019, and 2020 to EPA by September 1, 2020.

Ex. 5 Deliberative Process (DP)

[1] "Tetrachlorvinphos" includes phosphoric acid, 2-chloro-1-(2,4,5-trichlorophenyl)ethenyl dimethyl ester, EPA Pesticide Chemical (PC) Code 083701, and phosphoric acid, (1Z)-2-chloro-1-(2,4,5-trichlorophenyl)ethenyl dimethyl ester, EPA PC Code 083702.

- **Registration No. 2596-63.** Hartz agrees to voluntarily cancel this registration as of July 31, 2020. Hartz has not produced this product in more than five years and has no inventory; therefore, Hartz needs no existing stocks provision in connection with canceling this registration.

- **Registration No. 2596-49 (cat collar).** Hartz agrees to amend this registration to include a weight restriction in addition to the current age restriction; the adjusted label statement will read, **"For use on cats and kittens at least 12 weeks of age and weighting greater than 5 lbs."** Hartz will update the master label to include language used in the master label of EPA Registration No. 2596-83, including a Proposition 65 warning statement required for sale in California. This will allow Hartz adequate time to make necessary production changes and to avoid using two different marketplace labels during the same season.

- **Registration No. 2596-83 (cat collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

- **Registration No. 2596-139 (cat collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment,

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whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

- **Registration No. 2596-50 (dog collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

- **Registration No. 2596-63 (dog collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

- **Registration No. 2596-84 (dog collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration

amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

- **Registration No. 2596-139 (dog collar).** Hartz agrees to redesign the product and amend the existing registration to achieve an acceptable margin of exposure (MOE). Hartz will provide a proposal to EPA for review and approval by June 30, 2020. The proposal will include the following types of adjustments: a reduction in the thickness or width of the collar, a shortening of the length of the collar, or a combination of the foregoing adjustments. The adjustments will provide a collar with a formulation concentration of 0.88 g formulation/in (880 mg formulation/in), which includes 0.128 g (14.55%) of active ingredient per inch of collar, i.e., 0.128 g TCVP/in (128 mg TCVP/in).* The registration amendment will adjust the collar weight **only**; all remaining label language will remain the same. Hartz will file the amendment with the Agency by September 30, 2020. Hartz requests permission to continue producing and selling the existing collar through December 31, 2021 or for one year from the date on which EPA approves the amendment, whichever period is longer. Hartz intends to maintain the current EPA Registration Number to avoid discontinuance of state registrations and new state registrations fees, which would be excessive.

With the exception of the TCVP product registrations that Hartz will voluntarily cancel, Hartz understand that its proposed risk mitigation measures, described above, will address EPA's concerns with Hartz's remaining TCVP product registrations and allow them to remain in effect. If Hartz has an incorrect understanding following its most recent discussions with EPA, please let us know at the earliest opportunity.

Hartz has a long history of and abundant expertise and experience in making flea-and-tick collars, including those with TCVP as the active ingredient. Over the past 45 years, Hartz has developed and marketed collars with different active ingredients and concentrations. Data have demonstrated that efficacy is more a measure of the active ingredient in the collar and its percentage, versus the width and thickness of the collar. Our data and experience have demonstrated that the length, width, and thickness of the collars have varied based on marketplace demands, popular breeds of dogs, and their neck sizes. Early collars appear to have been designed to meet the needs of a 21-inch neck and were about 24-25 inches in length, with a weight of between 0.85 and 0.95 g/in.

As larger dogs became part of the urban family, history shows that collar lengths have evolved in response. The Agency has worked with Hartz and other collar companies and has allowed a weight range on the labels to allow companies to sell multiple collar lengths and weights to accommodate the market. As the collars became longer, they also became wider and thicker;

however, the early efficacy data was developed for collars that were thinner and narrower, approaching the proposed 0.88 g/in now being proposed as part of our voluntary mitigation effort, such that the efficacy data supporting registration was in fact generated on collars more in line with Hartz's current proposals. The Agency's files contain a number of these older efficacy studies, which were developed for collars weighing 1.0 g/in or less.

Hartz's proposals go back to the early weight per inch. By going back to a previously designed collar that meets the MOE needed for small cats and dogs, our laboratory has the engineering and manufacturing capabilities to allow Hartz to produce collars employing the same formula at the same concentration of active ingredient by choosing one of the provided combinations of width and thickness. Thus, Hartz will continue to generate a safe and effective collar.

Below are some of the measurements that we will be looking at to provide an MOE of greater than 1,000. The calculation is a measure of the proposed width and thickness, which provide the grams per inch:

- 0.370 X 0.131 - 0.86 gm/in
- 0.366 X 0.129 - 0.828 gm/in
- 0.368 X 0.132 - 0.88 gm/in
- 0.370 X 0.129 - 0.88 gm/in

Taking the g/in and multiplying it by the percentage of TCVP, we can determine the milligrams of active ingredient per inch of collar. Over the next several days, Hartz will be examining which thickness and width will provide the best collar and will propose these new dimensions and collar label weights for Hartz's TCVP product registrations. We look forward to discussing these calculations with you on June 11.

Sincerely,

JoeConti

Joe Conti
Sr. Director Regulatory, Research & Development

*Reduction of the formula (and associated TCVP) amount per inch of collar from 1.3 g formulation/in (for existing /current collar) to 0.88 g formulation/in (for proposed mitigated collar) results in a 1.47-fold lower application rate. Per EPA's exposure assessment methods, a 1.47-fold lower exposure and results in a 1.47 increase in the MOE. The 1.47-fold value represents the increase required for the lowest MOE (680 target MOE is 1,000; thus, 1000/680 = 1.47) determined in EPA's most recent revised risk assessment.